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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, June 21, 2017 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	Approved September 20, 2017

MEMBERS PRESENT

Susan Esposito, R.Ph., Professional Member, President
Hooshang Shanehsaz, R.Ph., Professional Member, Vice President
Bonnie Wallner, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Jay Galloway, Public Member
Gayle MacAfee, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Patricia Davis, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Meera Patel
Jessica Wearden
Lindsay Orr
Suzanne Raab-Long
Rich Palombo
Shelly Ide
Kevin Musto
Maggie White
George Fountzouky

CALL TO ORDER

Ms. Esposito called the meeting to order at 9:34 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to approve the meeting minutes for May 17, 2017. The motion carried.

UNFINISHED BUSINESS

Statutory and Regulatory Discussion

Telemedicine Pharmacy Regulations Changes. A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to table until the August 16, 2017 meeting. The motion carried.

Review of Regulation 19.0 - Define Acceptable Training. A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to table until the August 16, 2017 meeting. The motion carried.

PRESIDENT'S REPORT

Ms. Esposito provided the following report:

In meeting with members of various State Boards of Pharmacy at the NABP meeting, it is apparent that we are all at different levels of accomplishing ways to promote Patient Safety and to promote Pharmacists as a vital stakeholder on the Health Care Team. I have provided the members of the Board with a summary report of actions and some of the programs discussed during our meeting in order to save time at this Board Meeting. I will highlight some areas that are of interest to our current issues.

Veterinary Compounding: A resolution passed requesting a Task Force to develop model regulations for the compounding of animal products since DQSA and FDA guidance documents do not address this area specifically.

Definition of a Patient-Pharmacist Relationship: A resolution passed to convene a Task Force to provide a Patient-Pharmacist relationship definition as other healthcare groups have. To establish and provide our patients with an understanding of the trust, ethical, and patient-centric behavior that Pharmacists as their role in the patients' health care is rapidly expanding are dedicated to providing.

Uniform Unit-of-Use Packaging Standards: A resolution asking NABP to review existing packaging standards and establish consistency in labeling, dating, containers, etc. to provide safe and secure patient care in long-term care facilities, group homes and assisted living facilities as well as by individual patient needs.

Collaborative Practice Agreements: On June 2nd, NABP posted online a tool to use in modeling practice agreements, with the key points to consider. Also we heard from Illinois' Board of Pharmacy that they took Medication Therapy Management (MTM) definitions and used them for their model rather than call it collaborative care, which included all areas of Pharmacy Practice rather than addressing it separately by practice site.

Pharmacist Prescriber Authority: This was an involved discussion among the states, some have found areas of public health to focus on and expand Pharmacists roles.

Expedited Partner Therapy: allows for treatment of partner without being seen for STD diseases with RPH providing Azithromycin using EPT as patient name and obtained by cash, since insurance won't cover without patient specific name.

Oregon Board of Pharmacy approached by a Legislator who was an Orthopedic Surgeon and asked for them to address ways to provide better women's health choices to improve care of underserved patients by providing birth control by Pharmacists. Basically they developed with the Medical group a questionnaire completed by the patient and screened by the Pharmacist to qualify the patient for oral birth control, to improve care, reduce unwanted pregnancy, and decrease the State Medicaid costs. It was supported by the Women's Health Groups, and Planned Parenthood. This was an unexpected expansion of the Pharmacists role.

Inspection fines/citations by other states:

VA, NJ: ticket

Calif: 3 levels formal discipline, sanctions, citations (not reported)

Ill: Ticketing used not discipline, not reported to NABP

SC: citation regulation in 2014 not disciplinary, nor reported

Electronic Prescriptions: For Future Consideration

NY: Electronic Prescriptions only-mandated

VA: e-Rx by 2020 for controlled substances

Texting by MD on cell: most said not legal

Nevada: MD communications from hospital can be texted

Technician Training: A lot of discussion related to standardized technician education to help promote expanded roles for the Pharmacist with the technician trained to provide other areas of care.

I would like to make two recommendations for the Board to Consider.

Attending any National Meeting: whether ASHP, APHA, NABP, etc. you realize that it takes a few years of involvement with the organization serving on committees, Task forces and regional meeting to understand the group. NABP executive committee requires a multi-year commitment of those elected and you must be a member of a state board of Pharmacy to be a NABP committee member. It is for this reason that I recommend that Tejal Patel be our Delegate for the 2018 Annual Meeting. Tejal has attended a few annual meetings, is Secretary/Treasurer for District II and has been on a number of committees over the last few years. I would also like to suggest that we ensure that a Board Member is the Delegate and our Executive Secretary if attending be the alternate.

Board Member Terms: I would like to recommend that the Board look to have the legislative committee address what it would take to move the Board terms from 3 years with 2 appointments to a longer term of 4 or 5 years with 2 appointments. This came to my attention when I discussed with other attendees their terms and found that some were 5 years, others 6, and some had no limits. These states are the ones that have members on NABP committees, and the NABP Executive Committee. The fact that our Board will almost be totally replaced after our current terms expire, the learning curve that is needed to accomplish comfort in the Boards purpose takes time.

NEW BUSINESS

Ms. Esposito read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0005071	Philip	P	Bruno
A1-0005072	Olubukola	O.	Akinwekomi
A1-0005073	Daniel	John	Desch
A1-0005074	Sarah	E	Stieven
A1-0005075	Yassin	Ahmed	Nuru
A1-0005076	Irene	Marie	Lee
A1-0005077	Evelyn	O	Fisher
A1-0005078	Yesha	S.	Amin
A1-0005079	Yong Eun		Song
A1-0005080	Kailey	E.	Troutman

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002460	Kayla	M.	Jones
A7-0002461	Dania		Demashkieh

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0002005	CRx Specialty Solutions
A9-0002006	The Rite Pharmacy, Inc.
A9-0002007	Frederick Community Pharmacy
A9-0002008	Whiteville Community Pharmacy LLC
A9-0002009	D&D Pharma, LLC dba MedScript Long Term Care Pharmacy
A9-0002010	Veterinary Pharmacies of America
A9-0002011	VitalRx, LLC
A9-0002012	Hospital of the University of Pennsylvania Pharmacy
A9-0002013	Pharmetrics Specialty Group
A9-0002014	Park Irmat Drug Corp.
A9-0002015	TPS, LLC

A motion was made by Ms. Patel and seconded by Ms. Shanehsaz to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0002410	AmerisourceBergen Drug Corporation
A4-0002411	McKesson Corporation dba McKesson Drug Company
A4-0002412	Rochester Drug Co-Operative Inc. dba RDC
A4-0002413	PCCA
A4-0002414	Top Quality Manufacturing, Inc.
A4-0002415	Glenmark Pharmaceuticals Inc., USA
A4-0002416	PI Services, LLC
A4-0002417	Southern Anesthesia & Surgical, Inc.
A4-0002418	Southern Anesthesia & Surgical, Inc.

A motion was made by Ms. Patel and seconded by Ms. Shanehsaz to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

None

Retail Pharmacy Licensure Approval Ratification

A3-0001010	Community, A Walgreens Pharmacy #16532
A3-0001011	Weis Pharmacy #271

A motion was made by Ms. Patel and seconded by Ms. Shanehsaz to approve the ratification of the Retail Pharmacy application. The motion unanimously carried.

Non-Retail Pharmacy Licensure Approval Ratification

None

Outsourcing Facility

AA-0000041	Avella of Deer Valley, Inc. #38
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A motion was made by Ms. Patel and seconded by Ms. Shanehsaz to approve the ratification of the Outsourcing Facility application. The motion unanimously carried.

Pharmacist-In-Charge Interviews

None

Review of Revised Consent Agreement

Valerie Denise Barnes - A motion was made by Mr. Shanehsaz and seconded by Ms. MacAfee to reject the consent agreement as written. The motion unanimously carried.

Board Review of Facility Applications

Valeda Rx LLC (PA) - a motion was made by Ms. Robbins and seconded by Mr. Galloway to approve the application. The motion unanimously carried.

Clinical Specialty Infusions of Dallas, LLC (TX) - a motion was made by Ms. Wallner and seconded by Mr. Shanehsaz to approve the application. The motion unanimously carried.

Tailor Made Compounding (KY) - a motion was made by Mr. Shanehsaz and seconded by Ms. Esposito to table the application. The motion unanimously carried.

Central Admixture Pharmacy Services, Inc. (PA) - a motion was made by Mr. Galloway and seconded by Ms. MacAfee to table the application. The motion unanimously carried.

US Compounding, Inc. (AR) - a motion was made by Mr. Shanehsaz and seconded by Mr. Galloway to table the application. The motion unanimously carried.

Board Review of Pharmacist Applications

None

Continuing Education Review

None

Pharmacist and Pharmacy - Discussion/Action Items

None

COMMITTEE REPORTS

Legislative – Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz, Bonnie Wallner and Gayle MacAfee

Mr. Shanehsaz reported that he recently attended the Board of Medical Licensure & Discipline (BOMLD). He shared with the BOMLD the Board of Pharmacy (BOP) concerns regarding Emergent Care Facilities and the lack of regulatory oversight. He also expressed the BOP's concern for Patient Safety while practitioners are dispensing medication. He also discussed the need for more contact information to be included on the prescription blank due to the difficulty of pharmacist's inability to reach the practitioner in a timely manner, causing delay in medication dispensing to the patient.

Continuing Education – Bonnie Wallner, Tejal Patel:

No Report

Consumer Affairs – Jay Galloway, Gayle MacAfee

No Report

Professional Liaisons – Kim Robbins, Tejal Patel and Hooshang Shanehsaz:

Ms. Robbins stated that DPS has new officers effective July 2017. Currently a membership drive is in place.

Controlled Substance Liaisons – Tejal Patel, Hooshang Shanehsaz:

Samantha Netteshiem resigned as the PMP administrator effective May 31, 2017.

Ms. McCreary stated that during the last meeting of the committee there was concern expressed within the veterinary community regarding meeting the controlled substance registration continuing education requirement. Ms. McCreary stated during that meeting she would create a continuing education program for the prevention of diversion of controlled substances to be presented during the annual veterinary association meeting. Rich Palumbo, NJ Board/Express Scripts stated that there has been an increase in diversion within the veterinary community. It occurs when the human care giver brings an injured pet to the veterinarian for care. In some cases it is thought that the animal was intentionally harmed to gain access to drugs prescribed to the animal. The NJ Board is adding veterinarians to their PMP for this very reason.

Mr. Shanehsaz also stated there is new proposed legislation HB250 AN ACT TO AMEND TITLE 30 OF THE DELAWARE CODE RELATING TO OPIOID TAX. Original Synopsis: This Act imposes a tax on the first sale of opioids in the State at a rate of 10% of the purchase price. Prescription drugs used exclusively for the treatment of opioid addiction are excluded from the tax. Representative Keeley and Senator Henry are the sponsors of this proposed legislation. The Board stated that this could become a patient safety issue due to the possible decrease in access to drugs for patients. This cost cannot be passed on to the public therefore increasing costs to the seller.

INSPECTION and PMP REPORT - Michelle McCreary

Ms. McCreary stated she has completed the following inspections:

1 – Opening Inspection

1 – FDA Inspection requiring 3 days

Ms. McCreary informed the Board of 60 pending Walgreens in state pharmacy inspections that will be required to be completed sometime in August unless the ownership finalization dates are changed. Ms. McCreary also stated that all hospitals should be in compliance with USP 797 (now) & 800 (in the future). There are 72 sterile environments in Delaware that she is monitoring and inspecting for compliance with USP 797.

Mr. Mangler stated that a draft of the PMP contract with the new vendor has been reviewed. The PMP Administrator position was posted for 7 days which resulted in 12 applications. The applications are being screened for panel review. Veterans Administration Practitioner accounts are being setup. The Department of Defense is expected to request the same access in the future.

NEWSLETTER UPDATES

Newsletter topics were discussed by the Board for upcoming newsletter submission. The Board requested that the following topics be included in the newsletter: Regulations Changes that were effective 6/11/17, Immunization Approval Process for licensure, How to request PIC/Consultant Pharmacist interviews with the Board.

BOARD CORRESPONDENCE

Ms. Esposito read the following correspondence received:
Pharmacy & Therapeutics Journal - USP800 May 2017

Scripps-Safe Letter. The Board is deferring this to the Controlled Substance Advisory committee. It will be forwarded to that committee for review.

Containment Technologies Letter, the Board determined that Delaware regulation provides a more stringent standard. Therefore no further action is required.

OTHER BUSINESS BEFORE THE BOARD

Ms. Kelly stated that it is time for the review of the Multistate Pharmacy Jurisprudence Examination questions in August. The Board will be required to assign 4 individuals for the review one of which is the Boards attorney Ms. Kelly. A motion was made by Mr. Shanehsaz seconded by Ms. Wallner to approve Michelle McCreary, Tejal Patel and Mr. James Kaminski as the approved reviewers. The motion carried.

PUBLIC COMMENT

Mr. Musto is pleased to hear that the BOP is attending the BOMLD meetings to open a dialog between the Boards. Mr. Musto also stated he has been receiving phone calls once or twice weekly from vendors wanting to purchase his expired drugs. The immediate concern is why and what would they be doing with them. Mr. Musto met with the insurance commission regarding reimbursement being reduced or in some cases no reimbursement at all if the claim is below cost. Mr. Musto stated that Delaware Health Information Network is working on legislation to include R.Ph. and PharmD in their classification as a healthcare provider.

Ms. Lindsay Orr, attorney for Valerie Denise Barnes consent agreement reviewed previously on the agenda, wanted to make a statement regarding the Boards finding. Ms. Patricia Davis, DAG for the Board stated that no comment could be given regarding the consent agreement.

NEXT SCHEDULED MEETING

The next meeting is scheduled for August 16, 2017 at 9:30 Am., 2nd Floor Conference Room.

ADJOURNMENT

There being no other business before the Board, a motion to adjourn the meeting was made by Ms. Patel and seconded by Mr. Shanehsaz at 12:07 pm. The motion unanimously carried.

Respectfully submitted,



Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy